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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/580,704 | 05/30/2000 | George Peter Lomonossoff | DOW-04647 | 2167 |

7590 12/04/2001

Peter G. Carroll
MEDLEN & CARROLL, LLP
Suite 2200
220 Montgomery Street
San Francisco, CA 94104

| EXAMINER | |
|---|---|
| SANDALS, WILLIAM O | |
| ART UNIT | PAPER NUMBER |
| 1636 | |

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/580,704 | Lomonossoff et al. |
| **Examiner** | **Art Unit** |
| WILLIAM SANDALS | 1636 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Feb 12, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

### *Priority*

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The reference to the US Application Number 08/137,032 should be updated to reflect the issued patent therefrom. Also, the reference to the PCT Application should state that US Application Number 08/137,032 was a 371 of the PCT Application.

### *Oath/Declaration*

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

### *Specification*

3. The disclosure is objected to because of the following informalities: The Brief Description of the Figures does not recite Figure 3A and B, 5A and B, 9A and B nor 10A and B at the heading for each described figure.

Appropriate correction is required.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

5. Figures 4, 5, 8, 9 and 10 and pages 14, 17, 21 and 15 contain sequences which do not have sequence identifiers.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). (c)

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U. S. Patent No. 5,874,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a genus of a method of producing a modified plant virus while claims 1-9 of U. S. Patent No. 5,874,087 are drawn to a species of a method of producing a modified plant virus, and the species makes the genus obvious.

8. Claims 9-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-28 of U. S. Patent No. 5,958,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a genus of a method of producing a modified plant virus while claims 22-28 of U. S. Patent No. 5,958,422 are drawn to a species of a method of producing a modified plant virus, and the species makes the genus obvious.

See also MPEP § 804.

### *Claim Rejections - 35 USC § 112*

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4-6 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 4-6 and 15-16 recite the limitation "derived from". The limitation "derived from" is indefinite because there is no indication of the way it is patterned on the original and thus the metes and bounds are unclear.

12. Claim 9 recites the limitation "said nucleotide sequence" in line 4. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 9 recites the limitation "said plant viral genome" in line 5. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

15. Claims 1, 2, 7-10, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,316,931.

US 5,316,931 taught (see especially the abstract and columns 5, 6, 8, 9, 11, 12 and 14) a plant infected with a modified virus comprising modified viral nucleic acid which encoded a foreign peptide which was inserted in sequence coding for a viral coat protein, where there was no significant interference with the capacity of the modified virus to assemble. The peptide may be an antigen, and the virus may be a comovirus (an RNA virus). Also taught was a method of infecting a plant or plant cell with the modified virus.

### *Claim Rejections - 35 USC § 103*

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,316,931.

The claims are drawn to a plant infected with a modified virus comprising modified viral nucleic acid which encoded a foreign peptide which was inserted in sequence coding for a viral

coat protein, where there was no significant interference with the capacity of the modified virus to assemble. The peptide may be an antigen, and the virus may be a comovirus (an RNA virus). Also claimed was a method of infecting a plant or plant cell with the modified virus. The antigen may be from a foot and mouth disease virus, a HIV virus or a human rhinovirus.

US 5,316,931 taught the invention as described above in the rejection under 35 USC 102.

US 5,316,931 did not teach that the antigen may be from a foot and mouth disease virus, a HIV virus or a human rhinovirus.

It would be obvious to one of ordinary skill in the art at the time of filing the instant application to select a commonly known virus, as it is taught in the instant specification, to produce an antigen from the commonly known virus for the purpose of producing a vaccine, as stated in US 5,316,931 at column 14, lines 59-68.

One of ordinary skill in the art would have been motivated to select a commonly known virus, as it is taught in the instant specification, to produce an antigen from the commonly known virus to produce a desirable vaccine. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of US 5,316,931.

***Conclusion***

18. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61

(November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
November 20, 2001

TERRY MCKELVEY
PRIMARY EXAMINER